EXHIBIT F

REPORTER'S RECORD
VOLUME 1 OF 1 VOLUMES
TRIAL COURT CAUSE NO. DC-14-04220

CAROL CAVNESS	IN THE DISTRICT COURT
vs.	
TERESA KOWALCZYK, M.D., HUNT MEMORIAL HOSPITAL DISTRICT CHARITABLE HEALTH FOUNDATION d/b/a HUNT REGIONAL HEALTHCARE FOUNDATION and HUNT REGIONAL MEDICAL CENTER AT GREENVILLE, BAYLOR HEALTHCARE SYSTEM, JOHNSON & JOHNSON and ETHICON, INC.	DALLAS COUNTY, TEXAS 95TH JUDICIAL DISTRICT

TRIAL ON THE MERITS, MORNING

On the 30th day of September, 2015, the following proceedings came on to be held in the above-titled and numbered cause before the Honorable, Judge Ken Molberg Presiding, held in Dallas, Dallas County, Texas.

Proceedings reported by computerized stenotype machine.

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P R O C E E D I N G S

(Outside presence of the jury)

THE COURT: Everyone ready?

MR. PARRISH: Your Honor, we have a couple of housekeeping matters to address briefly this morning.

THE COURT: All right.

MR. PARRISH: Two should be very easy, and one I'll just give you a heads up on. And they relate -- the final thing I wanted to bring up with you just related to some arguments on the depo designations. First thing I wanted to take care of is we have our jury questionnaires that we wanted to return to the Court.

THE COURT: All right. Real good. I appreciate that.

MR. PARRISH: Certainly. May I approach?

THE COURT: I'll take them.

MR. PARRISH: Thank you.

MR. EDWARDS: Good morning.

THE COURT: Do y'all have your jury questionnaires?

MR. CAPSHAW: I think we shredded them already, Your Honor.

THE COURT: Double check.

MR. CAPSHAW: I will, but I know I shredded all the ones I have.

MR. PARRISH: Your Honor, the second matter that I wanted to bring up just very briefly has to do with the plaintiff's counter designations on Philippe Zimmern and this is an issue that Mr. Edward and I discussed yesterday.

They inadvertently omitted an answer from their counter-designations. I'm not fussing at them about that, but the answer does raise an objection that I just wanted to get on the record. And specifically, the question is asked beginning at page 81, line 9 through 19 -- excuse me, page 81, line 16.

Question: Dr. Zimmern, in your practice that some of your -- some of your patients who have had mesh completely removed still suffered from pain long after the mesh has been removed, but the cause of the pain was the mesh.

Answer: That is correct. Can I add one point? This was not just my opinion. This was the four people's writing this article opinion.

And that answer at 81, 21 through 23 was something that we would have objected to based on the previously filed motion in limine, fifth motion number one and number four dealing with other articles under 401 being not relevant because it was an article dealing with TVT exclusively, and Dr. Zimmern didn't have

any experience with PROSIMA™. So we would renew those particular motions and also assert the objection under 401 and 403.

THE COURT: Response?

MR. EDWARDS: This is the first I'm hearing about this because I thought we were willing to include it, so what I would say is we are referring to the article, and that is an article -- the answer relates to that article that Dr. Zimmern actually prepared with the three guys he says that have the consensus of the authors writing that article.

THE COURT: All right. But he's saying that this is a different product.

MR. EDWARDS: But it's still deals with synthetic mesh and also the Polypropylene heavyweight mesh that's actually included, the same with TVT as well as the PROSIMA™ device. And that's his experience as to -- as to what he has experienced with patients that he sees when he removes that mesh from them.

THE COURT: Well, I can see that the -- that the difference pointed out doesn't really matter in a certain part of this case. I mean, it's probably Polypropylene mesh that is allegedly the culprit, at least in a certain context. There's PROSIMA™ or whatever. I don't think I can quite slice it that thin.

I can -- I can see with respect to certain other arguments where it might be dissimilar, but with certain other allegations made by the plaintiffs it is similar, preclusive and travels across the board, and the difference being in the -- in the category he's looking at, the PROSIMA™ -- would be different than probably, and I don't know what they're talking about exactly in the article. But the PROSIMA™ would probably be different in a pore size and perhaps weight. Yet it would be similar in the context of other issues involved in the case but after degradation and curling and stretching and whatever.

So in any event, the objection's overruled.

MR. PARRISH: Thank you, Your Honor.

Finally, one last thing, and we don't want to take up too much of the time this morning with this, but I did want to bring it to the Court's attention. With respect to our designations of Jimmy Sanders, which we intend to play later today, plaintiff has lodged certain objections to our designations.

MR. EDWARDS: And I have those here, Your Honor.

MR. PARRISH: And I have also prepared our response to those, and I will give Your Honor a copy of

the deposition and --

THE COURT: Sanders objections by the plaintiff?

MR. PARRISH: That's correct. And I -- I've included our response --

THE COURT: Okay. Real good.

MR. PARRISH: -- within that document, so that you can take a look at that on a break, if you have time.

MR. EDWARDS: Your Honor, I don't want to -- just submit there are a lot, but I'd like to explain something. Of the lawyers up here, I was the only one at that deposition, and there is -- the biggest issue, as you will note, this -- our objection is that the defense lawyers prepared a chart, but they look almost like an index that corresponded with their notebook.

And they kept referring to that chart. That chart is a summary prepared by the defense lawyers, not by doctor -- not by the physician's assistant, Jimmy Sanders, therefore we believe it lacks foundation, calls for speculation. It's hearsay, and it was only created for litigation.

THE COURT: And Sanders is being tendered as an expert?

MR. BLANKENSHIP: He's a treater.

MR. EDWARDS: Treater.
MR. BLANKENSHIP: He's a PA, Judge.
THE COURT: So what is this so-called summary of?
MR. EDWARDS: They went through the medical records, and part of that summary within that is treatment by other physicians, Dr. Gray and Dr. Thurman, that -- or the PA, Mr. Sanders, did not even treat her at that time. What the -- what the defendants are doing is putting that chart, and they are saying, well, here's her 101st visit, here's her 98th visit.
That chart actually includes phone calls from the doctor's office, visits in which Mr. Sanders did not see her. And so it's very prejudicial in that they are saying look at all these visits that we pulled out of the records to show that Ms. Cavness would continue to go to the doctor over and over and over again.
And so we just feel that it's very prejudicial and that the reference to this the chart is hearsay because it's nothing that Mr. Sanders prepared. It was prepared by the lawyers and sent to him, and then they came and met with him and discussed that chart.
THE COURT: So the -- so I'm trying to grab onto the objection here. I mean, if they hadn't used the

chart and they'd just done it without a chart, it'd be okay?
MR. EDWARDS: Well, they could have referred to the medical records.
MR. PARRISH: Well, and, Your Honor, if I may respond, and then I'll try to go in reverse order. First of all, with respect to the last point, the summary was prepared, but it was authenticated by Mr. Sanders. During the deposition, he had the medical records present. He checked the medical records during the deposition, as you will see when you go back and review the deposition testimony.
THE COURT: Who is Sanders?
MR. PARRISH: He's a physicians assistant.
MR. EDWARDS: Physician assistant --
THE COURT: Okay.
MR. EDWARDS: -- at Hunt.
MR. BLANKENSHIP: Sandknot, Dr. Sandknot's office.
MR. PARRISH: That's what it is now, but it's Hunt Partners. It's disclosed.
MR. EDWARDS: He saw her from 2000 -- her being Ms. Cavness, 2000 to 2011, and then there was a break in time when he saw her in 2014, did some well woman exams when she would get sick.

THE COURT: So this includes stuff that goes --
MR. PARRISH: Back to 2006, I think, maybe 2005 on.
MR. EDWARDS: 2004. Yeah it goes all the way back to 2000, Bill.
MR. PARRISH: But he had the records in front of him. He authenticated the chart. You'll see that in his deposition. We have the medical records that have been already been filed as business records affidavits, so nothing's not in evidence.
THE COURT: Going on from that, what -- is there any other objections?
MR. EDWARDS: There -- well, in addition to the chart, there's quite a few references to collateral source and workers' comp, which we've objected to, and you'll note that and meet the objections.
MR. PARRISH: In response to that, there's nothing regarding payments from workers' comp. The plaintiff has already testified that she was injured on the job, so nothing about any payments made in any of our designations.
MR. EDWARDS: They --
THE COURT: What -- what is -- I mean, yeah, I've got to look at it. But what is the relevance

of 2005 or whatever it is? I mean, are we talking about stuff like she went in because --
MR. PARRISH: There is injuries on the job, and just to -- to illustrate the medical history, the symptoms of pain experienced by the plaintiff, it's not something brand-new just associated with this mesh. She's had lots of physical injuries. She's had lots of medication prescribed over the years.
THE COURT: Was there any tie in here to the -- to the current?
MR. EDWARDS: Well, Your Honor, no. And if you read the -- my cross of Mr. Sanders, I go -- I walk him through, did you find any problem with her vaginal wall or support? He says no. They -- what they're trying to establish is that she had chronic depression, chronic vertigo, basically went to the doctor all the time.
If you read Jimmy Sanders, our counters, he says, she did not have chronic depression, she did not have chronic vertigo. She -- and if it would -- if she would have had that, I would have put that in the medical record. You do not see anywhere in her medical records from 2000 to 2011 anything that he said was chronic -- a chronic condition. After he saw her again in 2014, it was chronic pelvic pain.
And so what they're trying to establish

is that she has vertigo. She has --

THE COURT: How would that be any different than if they tried to show you were a chronic defendant?

MR. EDWARDS: Well, Your Honor, my response is, if you'll recall the testimony of Ms. Pickel, her daughter, she said that she was basically in great health before she had this surgery, so it goes to discount that testimony.

THE COURT: Well, she probably lied to her mother at some time during her life, too. So.

MS. DOWNS: Your Honor, could I add one other thing that we think it -- makes it very relevant, and that would be expert testimony to which this will be important because her physical history and a few orthopedic injuries that she had added a load to her pelvic floor and primed her for the injury that she had in April of 2012.

This series of information that's coming in from the past of her medical history is all directly related to that. It's something that we need for our expert testimony.

THE COURT: Did somebody say all of that is relevant to -- I don't know. I see this fairly frequently, and it always puzzles me why, if they can -- if you can go after her for having other injuries that may

or may not be some way related, even remotely related to something of issue, why can't they -- they go into other things that your client's done?

MS. DOWNS: Well, Your Honor, I think there --

THE COURT: Or why can't they go into the other lawsuits and settlements and --

MS. DOWNS: Well, our position --

THE COURT: -- and fines by the federal government? And why can't they go into all of that? Why can't they -- why doesn't that just open the door, if we're going to attack somebody for every ding in their person, whether it be their real person or corporate person, why can't I just let all that in?

MS. DOWNS: Well, Your Honor, I think that those two things respectfully are different categories with Ms. Cavness.

THE COURT: I'll read it.

MS. DOWNS: Thank you.

MR. PARRISH: Thank you, Your Honor.

MR. BLANKENSHIP: Thank you.

THE COURT: We ready?

MS. GALLAGHER: Your Honor, I have one housekeeping matter.

THE COURT: Yes.

MS. GALLAGHER: When Dr. Sepulveda's testifying at some point this morning, I'm going to ask him to comment on some actual MRI films and a defecography MRI -- work on that word before we get the jury in here -- and so they're actually MRI images. Can we dim the lights for a couple of minutes, so he's talking about --

THE COURT: Yeah, just let me know.

MS. GALLAGHER: Okay. Thank you.

THE COURT: All right. Line them up, Robert.

THE BAILIFF: All rise for the jury.

(Jury in)

THE COURT: Be seated. Good morning.

JURY PANEL: Good morning.

THE COURT: You may call your next witness, Ms. Gallagher.

MS. GALLAGHER: Thank you, Your Honor.

At this time, we'd call Jaime Sepulveda.

THE COURT: All right. Mr. Sepulveda if, you would come forward and stand before the Court and raise your right hand, please. I know it's a little crowded up there. You -- that's fine. All right.

(Witness sworn)

THE COURT: If you'll be seated up here and please speak into that microphone directly.

DR. JAIME SEPULVEDA,

having been first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MS. GALLAGHER:

Q. Got to pull that towards you. You can pull the mic towards you, Doctor --

A. Right here.

Q. -- just so that everybody can hear you. Good morning, Doctor. Will you introduce yourself to the jury, please.

A. My name is Jaime Sepulveda.

Q. What do you do for a living?

A. I'm a gynecologic surgeon, a pelvic surgeon.

Q. Where do you practice?

A. In Miami, Florida.

Q. Doctor, I've asked you to come testify about several subjects in front of this jury today; is that right?

A. Yes.

Q. And are you going to be addressing for them the cause of Ms. Cavness's pain?

A. Yes, I will.

Q. And what pain syndromes she actually has?

A. Yes.

Q. Now, before you give the jury your opinions,

let's back up a little and tell them a little bit about you. All right.

You do not have a Texas accent. Where are you from?

A. I am -- I'm Puerto Rican. I was born, raised in Puerto Rico.

Q. And how long were you in Puerto Rico?

A. I was there until I came for my fellowship at University of Miami.

Q. Let's back up a little. Why did you become a urogynecologist?

A. First, I became a gynecologist. And, um, I -- I was -- I was the first doctor in my family, but I was around health care, and my mother was a social worker for the postpartum ward at my hometown in Bonsai, and as a single mother, she took me to the -- to the hospital, and I just -- I just grew up in that environment and eventually went on a scholarship to boarding school and University of Puerto Rico, a medical school there.

Q. Outline your educational background for the jury from time you went to medical school on.

A. Then from medical school, I did a fellowship on molecular pharmacology. I was attracted by bench work, and I did a fellowship there. It's -- it's a -- it's a year in the -- in the lab and then also at the University

of Puerto Rico. And then I -- I did some more research on -- on -- on renal cells and flow cytometry and cell cultures. And then I went to the clinical aspect of medicine through my residency in obstetrics and gynecology.

Q. When you said that you were doing pharmacology work, that's the study of medications?

A. Yeah. We -- we were -- what I did is optimized the -- the system to test different medications, different solutions on -- on cells.

Q. And so that was actually work in a laboratory?

A. Yes.

Q. And then you mentioned some other fellowships that you did.

A. Well, after I did OB/GYN and -- and an OB/GYN, I like the surgical aspect. I like the -- the interaction with -- with the female patient and in OB/GYN. Then I did -- I went to University of Miami, and it was at a time in which we were starting the subspecialty of urogynecology, which is known today as female pelvic medicine reconstructive surgery.

Q. All right. Let's back up a little. When did you get to Miami?

A. On 1990.

Q. And up until 1990, how many years of education

and fellowships and internships had you had at that point?

A. I've had my four years of -- of university, my four years of medical school, and my uro -- uro fellowship and my four years of residency.

Q. Before you ever got to the United States?

A. Yes.

Q. All right.

(Phone ringing in courtroom)

Q. And then when you got to the United States, did you go into private practice immediately?

A. No, no.

Q. Tell -- tell the jury a little bit about your work background and educational background once you got to the states?

A. Well, like -- like most people that finish medical school, I didn't come to Miami with a whole lot. I -- I -- I had a good position, an academic position, and it was a position working on the medical school and working on -- on the hospital and having the opportunity to do research and having the opportunity to do surgery and.

And I -- I -- that's when we started the -- we got all together at the -- we had a meeting at the NIH colorectals, urologists, gynecologists. We have

all this meeting, and we say, okay, there's a consensus to create this subspecialty. And I was one of the first probably 25, 25 doctors starting that.

Q. And you said at a meeting at the NIH.

A. Yeah. We --

Q. What is the NIH?

A. -- the National Institute of Health. My mentors at the -- at the university send me there, and they trusted that I was going to bring a report to create that subspecialty.

Q. And let's talk about that subspecialty. You said you and -- and about 25 other doctors started it?

A. Yeah. I think it was -- it was -- the group wasn't larger than 25. We cannot take the credit for -- for creating that subspecialty. It was there for us, but by all the work that all the other gynecologists through the years have done. But we -- we gave a structure. We actually made it in a way that someone can actually study and refer to it.

Q. And what's the difference between gynecology and urogynecology, what you do?

A. You know, when -- when we -- when we started looking at a name, we didn't come up with the name. The -- there were doctors, they'd say, okay, this is going to be urogynecology. Other places, they call it

pelvic surgery. And both terms really did not include the scope of what we were looking at.

We -- we didn't want to create a subspecialty that would just concentrate in surgery, that would -- but that would serve the female patient in general in those special needs of prolapse and incontinence and pelvic pain and -- and all the different dysfunctions that could happen to these patients.

Q. When did you actually enter private practice?

A. I -- I finish in 9 -- '92 at the university, and then I went to South Miami Hospital, and -- and the -- I was the first one doing what I -- doing pelvic -- pelvic floor work at that hospital in 1993.

Q. Did -- are you board certified?

A. Yes, I am.

Q. What are you board certified in?

A. I am board certified in obstetrics and gynecology. Then I have the -- I'm board certified -- I have the subspeciality board certification on female pelvic medicine. I'm proud to be on -- have been on the first group that completed this -- this certification.

And I'm also -- have a certification at -- type of board certification by Herman & Wallace Pelvic -- Pelvic Institute, which is called the pelvic

floor rehabilitation certification.

Q. So is it fair to say you're triple board certified?

A. Yeah, if you want to refer as triple board.

Q. All right. Triple board. And you mentioned that you were in the first group to receive the subspecialty certification in female pelvic medicine and reconstructive surgery. When was that board first offered?

A. The -- it was offered three years ago.

Q. And were you in the very first group to actually take and pass that certification?

A. Yes, I was.

Q. And then you also mentioned that you have a certification in pelvic floor therapy?

A. Yeah. It's an -- in pelvic floor rehabilitation, we don't -- I'm not a physical therapist. I don't see a doctor. I have a -- I got the certification on pelvic floor rehabilitation.

Q. And what does that involve, pelvic floor rehabilitation?

A. You know, it's -- before this, all the boards were for -- were for physical therapists. But there's -- there's this gap about -- from -- from the physical therapy area to the medical aspect, so up to -- up to

about three years ago, two years ago, actually, there was no way to get a board certification in pelvic floor rehabilitation, in something that I could tell my patients, yeah, someone -- someone actually tested me and shows that I'm proficient in giving pelvic floor rehabilitation.

And this is a key part of seeing these patients, being aware of that pelvic floor rehabilitation. So what you do is that you submit your case list. There's a board that approves it, and they ask the -- they tell you you can sit and take the exam. And that's what I did. I took the exam, and -- and after I was approved, even though ended up being a lot of work, it was a five-hour exam, standardized exam, but the most rewarding thing is that once you pass the exam, you know that someone validated that you know what you think you know.

Q. Okay. Do you belong to any professional groups?

A. Yes, I do.

Q. Tell the jury what some of those are.

A. I -- I belong to American Urological Association. I'm a fellow of the American College of Obstetricians and Gynecologists, and I'm a fellow of the American College of Surgeons. I'm a fellow of both

colleges, and -- and I'm a member of numerous pelvic floor societies, International Urogynecologic Association, American Urogynecologic Society, International Incontinence Society.

Q. What does it mean to be a fellow of the two colleges?

A. Well, once you -- once you pass your board, then you have to be in good ethical and moral standing, and they -- they evaluate your application, and you become a fellow. You're able to place all those letters that you see after you -- after you go and see a doctor, but you see all those letters afterwards, yes. They -- they say that you are -- you are -- that you are a fellow in good standing.

Q. You are also on the National Board of Medical Examiners?

A. That was -- that was my initial certification. I'm -- I'm -- I'm --

Q. You've also served on some committees at your hospitals?

A. Yes.

Q. And one of those things that you're still involved with is the Chairman of the Medical Arts Surgery Center?

A. Yes.

Q. What does that involve at your hospital?
A. This is the surgery center at the hospital, and what -- what I -- I mean, obviously I do surgery, and I practice medicine and bring my surgery -- my patients for surgery. But what I also do is that I over -- I look over credentialing. It means I -- I look at doctors that apply to have privileges at the hospital to work at the hospital.
I -- I look at credentialing. I look at the -- at the operations of the place in terms of safety. I -- I'm the liaison between the physicians and the organization. And I -- when joint commission comes in for accreditation and they want to talk to a doctor, I'm the one that talks to joint commission for the people that accredit the facility.
Q. You've also served on the Surgical Review Committee?
A. Yeah. Part of -- you don't become chairman of -- of the surgery center from when you leave -- when you leave your fellowship. You have to prove yourself through different areas and be devoted to -- to surgical review committees where you look at surgery outcomes, you look at results, and then you -- I also -- I'm the credentialing on all these different committees.
Q. Have you -- are you currently involved with

clinical research?
A. Yes, I am.
Q. Tell the jury a little bit about that.
A. I am -- I head as a principal investigator the fibroid registry. The -- it's a registry for uterine fibroids at my hospital, and I also head the pelvic floor or pelvic health study group. The pelvic health study group is -- is a group of doctors. It's all -- all -- all pelvic floor related, colorectal surgeons, urologists, radiologists, physical medicine specialists, physical therapists, all the doctor -- neurologists, gastroenterologists.
All these doctors that have to do with pelvic floor, we get together every other month, sometimes every three months if there's a summer in the middle. And we look at cases, and we bring cases. We discuss the cases, and everybody gives their own perspective on -- on these cases, and we come up with therapy solutions.
Q. And when did that start?
A. We -- we started that about two years ago. That's a continuing medical education activity, so it's -- we have to actually get the certification for it to be a continuing medical education activity.
Q. Have you also taught courses in medicine?

A. Yes, I have.
Q. Tell the jury what a couple of those were.
A. I -- I have -- I have taught courses within the industry and without the industry in both -- in both areas. And through all those courses, I've also traveled the United States, and I have help to put together different -- different departments.
Just -- just to mention a few, I helped to put together the pelvic floor -- the pelvic surgery section at the University of Puerto Rico with -- with a good friend of mine who is the Chief of that division. I have traveled to Columbia, put together an experimental surgery lab over there and years ago. So I -- I -- all over this time, I have been tracked to probably about a thousand surgeons that I have seen operate or they have seen me operate.
Q. And have you published on chronic pelvic pain?
A. Yes. I -- I publish in one of the proceedings in the past a long time ago.
Q. And have you published articles on a number of different topics?
A. Yes.
Q. Doctor --
MS. GALLAGHER: May I approach, Your Honor?
THE COURT: You may.

(Approaching)
Q. (BY MS. GALLAGHER) Doctor, let me hand you what is marked DX10660 and ask you if you can identify that, please.
A. That's my -- my CV.
Q. And does your CV contain a lot more details than what we've gone over today about your background and experience?
A. Yes.
MS. GALLAGHER: Your Honor, at this time defendants offer DX10660.
MR. MATTHEWS: We have no objection.
THE COURT: Admitted.
Q. (BY MS. GALLAGHER) That's fine. You can leave it there.
Doctor, you've been practicing medicine for a long time now?
A. It's 26 years.
Q. What are some of the things that you are most proud of from your career?
A. I'm -- I'm really, really proud of -- of the -- of what we put together -- what I put together when I -- at the very beginnings when I was starting in my community and there was no place for -- for a woman to go to a facility that would be dedicated to the care of

pelvic floor disorders.
Q. And so what did to you?
A. Well, first I convinced the hospital to finance it, and that -- I took a loan, and then put it together with the -- with the best -- best equipment that I could see. And I recruited the right personnel, all my -- the nurses and the assistants, recruited them, and made it -- made it a -- a simple place where they could come in and they wouldn't have to be waiting in a urologist office among all these guys treating their prostates or they -- or they would not have to be in an OB/GYN office with baby's running around. They could just get there and take care of their pelvic floor problems.
Q. And what was that called?
A. At that time, it -- we call it the Miami Urogynecology Center.
Q. And when did you open that?
A. It was about 1994.
Q. And was that the first such facility in the whole state of Florida?
A. That -- yeah. That was the first -- that was the first. And after that, there were a few -- few people fortunately reproduced that, and that's -- I'm good with that.
Q. And so now there are other such centers around

the United States?
A. Yes, yes.
Q. What's your other -- what's your favorite thing to do besides taking care of patients in your profession?
A. I -- I like to interact with my colleagues. I may travel and go see them do surgery. I may -- they may come and see me do surgery. And I just -- I just like that -- that intellectual interaction with all my -- all my colleagues. I have developed very good relationship with my -- with my -- with my colleagues over the years, and I like that interaction.
Q. Do you teach other surgeons how to do surgery?
A. I -- I do. I -- I -- I do not teach others at a student level. I -- I -- it's mostly skills, finesse skills that now I can learn from a lot -- sometimes I watch a surgeon do certain things, and I -- I acquire those -- those skills.
Q. Let's talk about your clinical experience. Tell the jury what your average day is like when you're at work.
A. Well, get -- get to the office, look at -- I have -- obviously I look the night before what I -- what I have. And on Mondays, I -- Mondays I have all my -- my major cases. Mondays is all my large cases.
Q. What is a large case?

A. The -- the big reconstructions, that's -- that's on Monday. And then on Tuesday, I see -- I see patients the whole day, and I talk to patients, do consultations. On -- on -- on Wednesdays, I do my -- my outpatient surgery. On Thursdays, I -- I see more patients.
On Friday, I take the afternoon off. I work only the morning doing procedures in my office. Most of my meetings for -- as medical -- as medical director happen around 6 o'clock, so when I finish my surgeries, I -- on my patients, I go there.
Q. What kind -- I'm sorry.
A. So that -- that -- that's it, essentially it.
Q. You said on Mondays you do reconstructive surgeries. What types of surgeries are you doing?
A. I do the open surgeries, robotic surgeries. I do vaginal surgeries. I do the approaches for pelvic organ prolapse, vaginal prolapse, bladder and rectal prolapses, and -- and patients that have had recurrent prolapse. I treat them, too.
Q. And then you said on Wednesdays you do your outpatient procedures. Tell the jury what kind of procedures you're doing with that.
A. It's mostly incontinence proceedings.
Q. Now, as part of your practice, do you read

diagnostics?
A. Yes, I do.
Q. Tell the jury what a diagnostic is.
A. Well, we -- in our facility, we have the -- the pelvic -- pelvic rehabilitation section, and one of my -- of my colleagues takes care of -- of that -- that area, and we devise the protocols. Then there is a diagnostics section that includes testing for urinary incontinence, for fecal incontinence, imaging, ultrasounds of the pelvic -- of the pelvic floor within the office.
And -- and -- which is not an office anymore. It's more like -- like a whole -- the whole facility. It's -- and we have a -- we do cystoscopies, too, on the diagnostic section. And then we have the actual consultations with the patients, place where we see patients.
Q. Do you actually read the films from ultrasounds and MRIs?
A. Yes, we do right at the office with the ultrasound, and we also do in the pelvic floor board.
Q. And is that something you do on a regular basis?
A. Yeah. I do it now on a regular basis after my radiology colleagues have taken me through -- through a few -- a few -- a few of the images.

Q. Now, when did you first encounter Ethicon?
A. I went to -- I went to the first activity with Ethicon when they invited me to see sling procedures in the -- in the lab, in a specimen lab.
Q. What is a sling procedure?
A. It's a procedure for urinary incontinence.
Q. And you said to a -- in a lab, a specimen lab?
A. Yes. It's -- a specimen lab is when you're -- learning anatomy in first year of medical school, you go to a specimen lab. They have -- they have a cadaver where you have to study ahead of time where you're going to look into, and we're not taking -- talking about a full -- a full cadaver. We're talking about a section.
And this is persons that have donated their body to science, and they would -- they -- they allocate this -- these specimens for -- to different facilities, to different -- different labs where you can learn.
Q. And why were you interested in going to these cadaver labs?
A. I was -- I was mostly interested on the -- on the activity of with being able to dissect, being able to -- to study the anatomy where I work every day. When -- once -- once you leave your first year of medical school, for many doctors that's the end of their training

on pelvic floor anatomy.
And I -- and I saw -- I always was interested, and I knew that -- so I knew that if I was doing surgery, there's nothing like knowing your anatomy when you're doing surgical procedure, nothing substitute that knowledge. I mean, yeah, you have to be skillful. You have to be delicate with the tissues. You have to do all things -- all things that we know that are right for the good healing.
But also you -- you need to know where you're going. You need to know what -- you need to know where you -- what you're doing in terms of the space.
Q. So was this additional training that you had once you got to Miami?
A. It's -- it was -- it was an opportunity to get -- to get into the cadaver lab. Unless you are back to first year of medical school, you don't get that opportunity again. In other words, you have your surgeon doing surgery on you after all these years of training, and that surgeon hasn't had the opportunity to go back to the -- to the -- to the lab and say, okay, what is it that I'm really doing here? What -- am I really doing what I think I'm doing on these proceedings?
Q. Did you eventually start teaching at these cadaver labs for Ethicon?

A. Yeah. I think that everybody caught -- caught word of my enthusiasm in my -- my devotion to develop this as -- as a tool where we could learn not just about the device but also about the anatomy.
Q. And did you eventually actually put together manuals for training in these cadaver labs?
A. Yes, I did.
Q. And we'll talk a little bit more about that later.
MS. GALLAGHER: Your Honor, at this time, we offer Dr. Sepulveda as an expert in urogynecology, pelvic floor -- pelvic floor dysfunction, and pelvic muscle rehabilitation.
THE COURT: Hearing no objection, very well. You may proceed.
MS. GALLAGHER: Thank you.
Q. (BY MS. GALLAGHER) All right, Doctor. You've done some work in this case?
A. Yes. Yes, I have.
Q. And tell the jury what you've done in order to get ready to give them or to prepare to formulate your opinions and then give them to the jury today.
A. Well, I have -- I have seen multiple records from -- from all the providers, and I have seen the -- the records from the providers, the records from the

hospital. I have seen operative reports. I have seen imaging. I have seen MRIs, ultrasounds. I have seen deposition transcripts. I have seen exhibits from -- that have been given to -- I have read articles again that I have read in the past, and I have had to read them -- read them again and done -- which is -- which is actually very, very good. I get to polish my knowledge, and -- and these are the documents that I have examined.
Q. And are we compensating you for your time that you've spent doing this?
A. Yes.
Q. About how many hours do you think you've spent in total reviewing the medical records, looking at the depositions, re-familiarizing yourself with the literature, educating me about the medicine in this case? What's your estimate of the total amount of time you've spent?
A. This is the first time that I go through all this, so have to be about 150 hours.
Q. And what are you charging per hour?
A. I charge $500 an hour.
Q. And is that whether you're reviewing records or testifying?
A. Yeah. It's -- it's -- it applies to everything. There's -- there's -- there are other

scales, but I just -- it applies to every hour that I spent.

Q. All right. Now, have you been in Dallas several days this week?

A. Yes, I have been.

Q. When did you get in?

A. I got in on Sunday.

Q. And why have you been here since Sunday?

A. Because I have -- I had to meet with you and go over the slides.

Q. On Sunday.

A. I had to -- I had to actually see that and see that and meet with -- with the team about the images that I -- that I felt were relevant, and -- and you-all -- we all worked very hard, prepared well, so I had to prepare to be efficient on this.

Q. And were you here in the courtroom when Dr. Margolis testified yesterday and the day before?

A. Yes. Yes, I was.

Q. And why were you in the courtroom while he testified?

A. Because I never -- I never done it, and I wanted to make sure that when I come in here, I could do it right.

Q. Did you also --

(Laughing)

Q. -- want to the listen to his opinions?

A. Yeah. I got to listen to his opinions.

(Laughing on jury)

Q. But it's mostly so you could see how this process worked?

A. Yes.

Q. All right, Doctor. I want to talk to you now about -- I'm going to call this anatomy 101. I went through this with the jury in opening, but I don't think anybody who's really qualified to explain this to them has done it.

MS. GALLAGHER: Your Honor, may I have Dr. Sepulveda step down and talk about something?

THE COURT: You may.

Q. (BY MS. GALLAGHER) Doctor, if you'd come on down, please.

A. Yes.

MS. GALLAGHER: This is what we used in opening, David.

Q. (BY MS. GALLAGHER) All right, Doctor.

A. Go get my pointer.

Q. Let me get it to you, so you can -- and, Doctor, our blue lady over here, would you just explain the anatomy and where the various organs are that we'll

be talking about today?

A. Well, we'll be -- we'll be talking about the bladder. We'll be talking about the vagina. There's no -- no uterus in here. And this is the rectum, and you -- the perspective here is we're looking at someone from the side. We --

Q. So is the --

A. -- that is standing like this.

Q. And this is the front over here?

A. Yeah.

Q. Okay.

A. These -- this bone here, this bone here is the pelvis. This is the bone that you feel when you press on the pelvis.

Q. And then over here on our colored picture, explain to the jury what this is. What is that?

A. This is the presentation of a rectocele, and this is -- the vagina, and this is the division. This tissue divides from the bottom up, divides the tissue between the rectum and the vagina. And not surprisingly we call it the rectovaginal tissue.

Q. And what causes -- so is this actually the rectum?

A. Yeah. This is -- you -- you urinate through here, and this is -- you defecate through here. Just

there's defecation comes right through here.

Q. And so is this actually part of the rectum that is coming out of the vagina?

A. Yes. It's not a normal -- not a normal part. This is a prolapsing part. It's protruding through the vaginal tissue.

Q. And what generally causes a prolapse?

A. It's a variety of conditions, but in essence, it is the weakness of the tissue. Each individual have different strength of tissue, and there's -- there's a weakness or tissue becomes delicate and in here. And they -- it can also be the support of the vagina is lost. There's -- there are muscles that run all around here, and when those muscles become flaccid or break, the prolapse comes in.

Q. And can you get a prolapse gradually?

A. You -- you can get it gradually, or you can get it quickly.

Q. And when you get it quickly, what generally causes that?

A. The -- the most recent reason for that is accumulation of stress in that -- in that area, and it's -- it's that the tissue become indurated, they become contracted. The muscle becomes hard, sometimes doesn't have the normal oxygen supply, doesn't have

the -- all the fluids, and it loses elasticity and on the southern force just breaks. In other words, it's hanging by a few threads, and then it breaks, and then we see the prolapse.

Q. What breaks?

A. The -- the muscle -- the muscle -- the muscle breaks.

Q. All right. Let me get another board up here and see if you can explain this. And, again, we start with our -- thank you, Doctor. We start with our blue lady, and this is some -- this is the anatomy without a prolapse, right?

A. Yes. That -- in here, we -- we just remove the organs, and -- and this is as -- as -- as complicated as this would be, when you dissect a cadaver, when you're in the lab, it looks exactly -- exactly like this. That was my first one, and when I saw this diagram, and you see all these fibers of muscles. This is not just a representation. This is a very accurate presentation of the muscles.

Now, what you have is that this -- these muscles act like a hammock. If you -- obviously this is part of my spine, and this area here is my hips, and those muscles act like hammock. When you're walking around, they hold things together. So through here,

through here we have the opening of the -- opening to the -- to the rectum. And through here, we have the opening to the vagina. And this division here corresponds to this area here on the division between the vagina and the rectum.

But this essentially the muscles that hold to the bone, so something that I all -- I always mention when I'm teaching anatomy class is the closer you get to the bone, the thicker the tissue gets. And you -- you -- you may see that, those of you that -- when you're having a steak, you see that the muscle holds right through your bone there with that -- with an attachment, with a stronger attachment. That's what you have. That's when you see right -- right here an attachment of the muscle to the -- to the bone.

Q. And what are these back here?

A. These are more muscles. This -- this muscle we call it the coccyx pubis muscle. There are tendons and the tendons in this area, this is -- we call this the sacrospinous ligament because it goes from the sacrum to the spine. That's the sacrospinous ligament. And this muscle is the coccyx pubis.

Q. All right. Now, we've got a representation here of some of the muscles, but does that include all of the muscles in the pelvic floor?

A. No, no. This is -- this is when you get on -- dissect everything out, you're able to identify these muscles.

Q. About how many muscles are there in the pelvic floor in total?

A. There are 650 muscles in the whole system, and most of them are concentrated in the -- in the pelvis and in the neck.

Q. So 650 in someone's entire body?

A. Entire body.

Q. And how many or what percentage are in the pelvic floor?

A. There are easily 150, and there are variations, and there are different distributions and how high you go on your anatomy boundaries, but it takes -- it's easily about 150.

Q. Okay. We're not going to talk about 150.

A. No, no, won't put you through that, no.

Q. All right. So we're going to focus on these muscles down here. Now, you said that if somebody has an acute or a sudden prolapse that the muscle has broken.

A. Yeah. The --

Q. Explain to the jury using the diagram what you're talking about.

A. Well, the -- there I have mentioned two things

that I -- that are -- that the tissue, how -- how -- how elastic, how pliable, how strong the tissue is in -- in here. And the other thing is that the tone and the support that the -- that the muscles -- that the muscles give.

So when you have just a tissue that just becomes over time a little more elastic, you -- those are the patients that come and tell me, well, I felt something down there, then something a little later, something at -- eventually, you know, it's going to be -- at the beginning, I really ignore it. But I -- I come to a point in which it's bothering me, so I need you to tell me what it is, or they go to the doctor and the doctor send them to me to see what -- what it is.

When you see -- when you see a sudden quick appearance of the prolapse, there's a muscle that broke. It's -- if you see suddenly, it broke.

Q. And how do you know that? Why -- explain to the jury why that is.

A. Well, because that progressive -- progressive enlargement is due to the pliability. The tissue become very elastic. It just starts -- start distending under the pressure. Right now when I'm talking, I'm putting pressure in the abdomen. So the pelvic floor moves -- moves in. Every time we move, every time we go

splinting, we go running, we exercise, we lift something, that pelvic floor moves. And sometimes you see that that comes -- that bulging comes out, and I -- they come up. But when the muscle is broken, it just suddenly comes out.

Q. And is that because there's nothing holding these up anymore?

A. Right. Now, you don't have these -- we call these the levator plaits. This levator plait then detaches from here, and by the way, you don't have to detach the whole thing. You can detach only a few fibers, and it's like when you have -- when you have a curtain that is hanging and hanging from the rail, sometimes those curtain, a few -- I don't know, it happen -- it happens to me all the time, shower curtain, a few come off, and you know that it sags. That's exactly what happens to a muscle.

Q. And that's what leads the organ, in this case the rectum, to sag into the vagina?

A. Well, once -- once they break, this opening is not anymore a small opening. It just -- it just opens. When it breaks, the hiatus, the opening of the organs, we call it the hiatus, the hiatus opens up. That's -- that's what happens, just opens up and allows for the organs to have other pressure come down.

Q. And let's talk about Ms. Cavness. Did she have a muscle that broke?

A. Yeah. I --

Q. That --

A. -- that's exactly my opinion.

Q. Okay. And point out to the jury here the muscle that you believe Ms. Cavness tore.

A. Based on the symptoms and based on what has been documented on her records, I am -- I am -- I am certain that that -- there's a muscle that broke right around here, right here in the front. The attachment of one of these muscles broke and --

Q. What do you -- oh, you want a marker?

A. Yeah.

Q. What color would you like?

A. Let's -- any color is --

Q. Got all sorts of colors.

A. I don't want to be --

Q. No, no, no, here. Let's use we'll -- hold on. I can't get in this box. Let's see if green works. Thank you.

A. And these are -- the fibers, when you look closer, it looks -- it looks a lot nicer, these fibers. And there's an attachment here that this area around here goes from the ischial spine to behind this bone, which we

call the pubis. That -- that line, we call it the arcus. It's like a beam.

Q. We call it the what?

A. Arcus.

Q. Arcus?

A. The arcus. It's like a beam, and that beam holds the roof of the vagina.

Q. And you talked about the ischial spine. What is that?

A. Here, that's this bone in support.

Q. And do you have one on each side?

A. One on each side. It's you -- that's -- that's what -- how every time I teach someone how to -- I say put your finger, you feel the ischial spine. That's the landmark for everything else that you --

Q. What do you mean when you're teaching somebody how to feel?

A. When I -- when I'm teaching a surgeon or I'm teaching someone that says, okay, take -- give me a tour of the pelvis, give me a tour of the pelvis, I -- and I'm going to go ahead and tell them, okay, let's see for the things that you feel quickly, and that is the ischial spine.

Q. And you say when you feel. Is this through a vaginal exam?

A. Through the vaginal exam. That's the landmark, and you feel it, and it's invariably about -- about 8 centimeters from the most -- from the outside in, and you feel that. It's like an knuckle. It feels just like your knuckle.

Q. So if you were coming -- if you were doing a vaginal exam, you're coming through here?

A. Right.

Q. And this is what you're feeling?

A. Right. And then -- and then in here, it looks really long, but it's about 8 centimeters.

Q. And why is it -- and why do you need landmarks? What's the point?

A. You need -- you need to know where you're going exactly. You need to know where -- I'm sorry. I think I said I was going to cancel this.

Q. We don't like those exhibits. Okay.

A. So this -- this -- from here to here is 8 centimeters, and this is a landmark. You need to be able to feel the landmarks. You're not going blind. You're going by landmarks.

Q. And you say by going by landmarks. Then you know what muscles and what organs, where they are based on what you're feeling?

A. Right. I know that there are 10 centimeters

from here to here, and I'm going to get -- and there I know exactly where I'm going to feel it.

Q. And that's the anatomy that you learned first in medical school and then later in these cadaver labs?

A. If you don't go back to a cadaver lab and you just take what you learned in medical school -- in medical school, it's -- it's just too shallow of a knowledge.

Q. Okay.

A. You need to know -- know this.

Q. All right, Doctor. I'm going to -- I'm going to move these back. You can go ahead and take your seat. Claustrophobic, need space.

All right. Let's talk generally kind of broad view about your opinions about what happened with Ms. Cavness.

A. I -- I think that -- my opinion is that Ms. -- Mrs. Cavness had an acute injury to the pelvic floor. An acute injury means something happened suddenly and quickly.

Q. And she had an acute injury to her pelvic floor, and that led to what?

A. That -- that led to the pain and that led to the prolapse.

Q. And are the pain and prolapse the same thing or

two different things?

A. They are two different conditions.

Q. And, Doctor, I'm going to be asking you about your opinions today. And will you give those opinions based on reasonable medical probability?

A. Oh, yeah, yes.

Q. That's a standard that we use. If I asked you to give your opinions with a hundred percent accuracy, could you do that?

A. I -- I think it's well-understood that there's -- nothing is a hundred percent in life.

Q. And therefore there's nothing that's a hundred percent in medicine?

A. No, absolutely not.

Q. All right. So we're talking about reasonable medical probability. And you've come to these conclusions based on what?

A. On the -- on the review of the medical records, on the review of the history, on the images and the -- what each one of the surgeons not only documented in their records but also spoke about, and finally the -- the imaging, the view of the -- of the images.

Q. And how about did you have an opportunity to examine Ms. Cavness?

A. I did have an opportunity, yes, to

examine Ms. Cavness.

Q. The jury knows we call those IMEs?

A. Yeah. It's called an independent medical examination.

Q. And did you come to Texas to perform that IME --

A. I did --

Q. Up here?

A. -- under -- under court order, under court order. I --

Q. And are part of your opinions based on your examination of Ms. Cavness also?

A. Yes.

Q. All right. So you said there were two different things that were going on because of this acute injury, the pelvic pain and the prolapse, right?

A. Yes.

Q. All right. So I'm going to talk about prolapse first and talk about that, and then we'll talk about the pain, all right, that Ms. Cavness has.

A. Yes.

Q. All right. So you've told the jury what prolapse is and that Ms. Cavness had an acute injury. What is the acute injury she had that caused the prolapse?

A. It was the -- by the way, defining -- defining prolapse, I want to make sure that I clarify that prolapse is when the organs -- the internal organs of the pelvic prolapse come through -- through that area that we have defined as a hiatus, as an opening. And is -- it's a frightening thing when you actually see -- see that -- that there is a bulge coming through an area where you have -- you have raised knowing that there's no bulge that's going to be there.

Q. And what happened with Ms. Cavness that caused that bulge or that prolapse?

A. The -- there was a -- a lifting either of a -- of a -- it was an injury either at work or lifting a pot based on the -- on the review of the records. One of those things made an acute force or produced an acute force that followed immediately with the onset of pain and prolapse.

Q. And where did you see this acute injury?

A. At -- I saw the -- the description of the consequences of this injury. I saw the -- this in the medical records from the visit to the emergency room before she went to see Dr. Kowalczyk.

MS. GALLAGHER: T-Zady, will you please pull up 10018.12, please.

Q. (BY MS. GALLAGHER) And, Doctor, this is -- do

you recognize this record?
A. I do.
Q. And what is -- where is this record from?
A. This is from the visit to the emergency room on -- on -- on April 20 -- 21st --
MS. GALLAGHER: Is this in y'all's way? And --
A. -- of 2012. I apologize for interrupting.
Q. (BY MS. GALLAGHER) And we've highlighted portions of these records, but you've reviewed the entire record?
A. Yes, I have.
Q. There's stacks of them, right.
A. Yeah.
Q. There's a lot of records. And the pain level of 7 out of 10, what does that mean?
A. 7 out of 10 -- out of 10 is a significant pain. It's -- that -- that's called a visual analog scale, and you see at one of the -- at one of the -- of the ends on the -- in the one, it's -- you have a little face with a with a little smile, it's content, and you have a 10 out of 10. There's a grimacing or actually crying with a pain. So that's -- that's the range, and this is from 0 to 10. In the visual analog scale, she was 7.
Q. When Ms. Cavness had this acute injury, was

it -- this lifting injury, was there anything that had primed her for sustaining that kind of injury?
A. I -- I do -- I do believe that patients that have had a history of injuries in other parts of their body, and you cannot put just one -- one -- one -- the pelvis as an isolated place. The pelvis is part of a person, and the person has different -- different areas, not just the pelvis, and different parts of the body can -- can be -- can be hurt. And when you have demonstrated consistently that you can hurt other parts, it's not surprising that you might have another injury elsewhere.
Q. Why is it that if you injure your plait -- injure yourself somewhere else that it can affect the pelvic muscles?
A. The -- when you -- you can injure -- you can injure a leg on -- on -- a leg, and then as you walk around, you walk in balance, and your -- your muscles compensate for it. And unfortunately we also age, and we start putting more pressure in -- on one area over another and develop certain postures.
We develop certain -- we call it gait, the way you walk. And all these things end taking a toll on the muscles. You adapt. We are -- our bodies are so smart that they keep adapting. They adapt to

a -- in a way, and you can get injured, and you compensate and adapt in other ways. But that puts a load in -- more -- more load in other areas that were not -- were not intended to be there.
Q. How about pregnancies, can that affect?
A. Absolutely.
Q. And did Ms. Cavness have pregnancies?
A. She had -- she had two -- two babies.
Q. How about smoking, can that affect your pelvic muscles?
A. You know, that -- I -- I -- I can -- I can cannot encourage my patients more about stop poisoning theirself -- poisoning themselves with cigarette smoke.
Q. How does that affect the muscles of the pelvis?
A. There's -- nicotine -- and by the way, nicotine's just one of the components. You have -- and this is just general medical knowledge. You have carbon monoxide. You have all these different substances. At the moment that you take them, yeah, it gives you that reward on your -- on your brain receptors. It feels good. You -- you get a smoke, everything feels a little better, and it has -- maybe an analgesic effect in some way.
But on the other side, it's acting physiologically by contracting your blood vessels,

pro- -- putting profusion, thus profusion to the -- to the muscles. The muscles get dehydrated. They get what is called atrophic, they shrink. They -- they -- you have the -- the blood vessels again producing that -- that changes, and the blood -- and those change in the blood vessels produce little clots that will pollute those vessels eventually and the -- it's a toxic effect.
Q. So let's get back to Ms. Cavness. When she arrived to Dr. Kowalczyk's office I think that following Monday after she injured herself over the weekend, did she have options as to what to do with her rectocele?
A. Yes, she -- yes, she did.
Q. And what was -- what are some of the things that she could have done or not done to treat her rectocele?
A. You -- you can -- you can observe it. You can always observe a rectocele, but I -- but I also understand that many times I have -- I spent more time reassuring my patients you're going to be okay observing this rectocele -- and we'll figure -- we'll figure this out.
Q. And by observing, what do you mean?
A. It's -- we call it -- observing is what we call it. In medicine, we call it watch -- watchful wait. You watch it; you wait. And that's -- that's -- that's an

option. That's always an option for the patient. You watch it; you wait. It's -- the other -- the other option is to have -- to have surgery.

Now, once -- once the -- the prolapse comes out -- and we're talking just about prolapse. Once the prolapse comes out, we know that pelvic floor exercises, pelvic floor rehabilitation may not be as effective as when we have a prolapse holding -- holding inside. In other words, you can have a little -- a little prolapse in the inside, and you can -- you can probably rehab those muscles and bring it back, assuming obviously that there's no pain.

Q. And what option did Ms. Cavness choose?

A. The records show surgery.

Q. And was this -- is this a surgery that you usually do the day -- the next day? Is it a hurry-up-and-get-it-done surgery?

A. I -- I don't.

Q. When did she actually have surgery?

A. The -- the next day after she was seen by Dr. Kowalczyk.

Q. And what time did she have that surgery?

A. Around 5 o'clock in the afternoon.

Q. Is that unusual?

A. That -- that is unusual. In my practice, it

is.

Q. And what is your understanding from your review of the materials in this case, the medical records and the depositions, as to why Ms. Cavness wanted surgery so quickly?

A. I -- I think that the -- the big factor was the pain, a 7 out of 10 pain.

Q. And do you usually have pain when you get a prolapse?

A. Not unless you have an injury to the muscle.

Q. All right. Tell the jury why those are two different things.

A. There -- these are two different things because as we explained, there's the area of support in the tissue, in the -- in the actual tissue that divides the vagina from the rectum in this specific case. There's the actual tissue. That's one thing with prolapse, it becomes relaxed, and you get the prolapse.

Now, when you have a -- a -- a breakage of the muscle, it's not only contributing to your prolapse, it's not only making your organs come to the outside, it's also hurting.

Q. And the hurting is from what?

A. From the -- from the injury to the muscles.

Q. The tear?

A. The tear, yeah.

Q. Now, you know, we all know that this surgery was performed using PROSIMA™.

A. Yes.

Q. And was that a -- an appropriate decision for Ms. Cavness to do various surgeries that she had augmenting the PROSIMA™?

A. I -- I agree that that was the right decision to use.

Q. And why is that?

A. Because there's certain criteria when you look at the prolapse. I look at the description of the prolapse, and there's certain criteria that is used to it. And that criteria is developed through your history and physical examination.

Q. And what is that criteria?

A. We -- we did a mnemonic. It's called RULES.

Q. RULES?

A. RULES. The way I teach it is RULES.

Q. R-U-L-E-S?

A. R-U-L-E-S. And the first R is to -- square R, two Rs.

Q. Okay. What's the first R?

A. The first R is recurrence.

Q. What does that mean?

A. And recurrence means that someone has repaired this prolapse, and it came out. You're going to tell me, well, Ms. Cavness didn't have -- didn't have a prolapse before. You -- within recurrence, we include those patients that have had a hysterectomy. The -- the only organ in the whole pelvis that connects the anterior and posterior portion, the lateral portion, and all the ligaments is the uterus. The uterus connects everything. It's central to the pelvis.

MS. GALLAGHER: May have him step down, Your Honor?

THE COURT: You may.

Q. (BY MS. GALLAGHER) Doctor, explain to the jury what you're talking about when you say it's the only organ that connects to things.

A. It's only -- hysterectomy, there's the cervix. There's the uterus here. Uterus -- this is the uterus here. It connects the uterosacral ligaments. It connects the part of the -- of -- the posterior part of the -- of the connective tissue. It connects this. It connects the anterior aspect of the connective tissue. Everything is connected to this area right around here.

Q. And why is that important?

A. Well, in Mrs. Cavness, she -- she had a hysterectomy before, so you don't -- you don't see -- you

don't see a uterus.
Q. No uterus.
A. You don't see a uterus here. It's just the vaginal -- the vaginal wall, so part of the art for recurrence. Can I --
Q. Yeah.
A. -- the art of RULES -- the art of RULES is that previous hysterectomy. The other thing is the lack of rugae. Rugae are creases.
Q. And that is R-U-G-A-E?
A. Yes. Like -- like we -- we call -- there's words in Spanish that describes it, you know, like the creases here are -- we -- very similar, are rugaes. But it's -- it's a rugae. And the rugae is, you see those little creases, and the creases are formed from the connective tissue, the tissue that gives support under the vaginal tissue.
If you see that there -- when I examined the patient, if I see that there are rugae, I know I'm going to find some fiber connective tissue back there.
Q. Okay. Wait, wait, wait. Can you draw Rugae?
A. Yeah.
Q. All right, Doctor.
MS. GALLAGHER: If you would come -- may he step down, Your Honor?

THE COURT: Yes.
Q. (BY MS. GALLAGHER) Can you please draw some rugae for the jury?
A. So when you examined the patient, this is the vulva, and the patient with and the patient without -- with prolapse, you see that the lower aspect, the rugae. This is the opening. There are rugae here, but then once you get up here, you don't see -- you don't see much. There's nothing giving -- giving that rugae appearance. There's no tissue underneath giving the rugae.
Q. So would this be -- if this is the -- this is the entrance to the vagina?
A. Right.
Q. And so this is like lines?
A. Like lines right here.
Q. And that -- the lines tell you what?
A. It looks like -- it looks like -- like this paper.
Q. Oh.
A. And then when you have no tissue underneath, it looks flat.
Q. And what's the significance of having tissue -- yes -- or not having tissue underneath?
A. Well, if I -- when I get back to the OR, to the operating room, when I take the patient to the operating

room, I can tell -- I can -- I know there's fiber connective tissue underneath. And the -- if I have fiber connective tissue, I can do a repair that does not require reinforcement using a graft.
Q. What --
A. I can just put absorbable sutures.
Q. What is this fibrotic tissue? Tell the jury what that is.
A. Fiber connective tissue --
Q. Yes.
A. -- is a dense tissue that gives support. It gives support to the -- to the -- to the vagina. If you really look at the covering of the vagina, it's a very soft, very soft tissue, very elastic tissue. But underneath what you have is that -- that tissue that gives the -- it's -- it's a contract -- it's a stiffer tissue on that area, and it has the nice rugae.
So I know all I have to do is put together a few stitches, but when you go to the ope- -- through the vagina, you don't see much of that.
Q. Okay. So one was recurrence, right?
A. Yes.
Q. And then the rugae, which is here?
A. Yeah.
Q. Now, we're up to U. What is U?

A. The -- the --
Q. That's a --
A. It still belong --
Q. -- r is square?
A. -- to the rugae, to the rugae.
Q. So we're at L?
A. We're at L. And the L is the location, where is the prolapse located at.
Q. And why is that important in your determination of whether or not you would use a product like PROSIMA™?
A. Well, there's -- there's evidence published -- evidence published in -- in anatomic and in the surgical anatomy in which we -- it's been proven that the tissue on the lower part, it confirms the observation that we have had for years. In the lower part, there's more fiber connective tissue. In the upper part, there's less fiber connective tissue.
So it solves the dilemma that I found probably on the first 10 years doing surgery, which is I start dissecting and always found I have no tissue up there to put together. So you -- you end up putting fine sutures. The upper part of the vagina --
Q. And just to orient the jury, when you're talking about the upper part, we're talking about up here?

A. Yes.
Q. And so this is where you would see more rugae?
A. More dense fiber connective tissue in that area around the perineum.
Q. What's the perineum?
A. The lower part.
Q. Down here?
A. The division between the vagina and the anus. So once you get to the -- to the middle part, there's less tissue, and once you get to the upper part, there's almost no fiber connective tissue there, not much support. What you have is the vaginal layer, and you have the rectal layer or the peritoneal layer.
Q. And so if you're -- is that -- when you say location, do you mean where the prolapse is actually coming through?
A. Where the prolapse is actually at. Where's my -- where's this prolapse being located? Is this in the lower third, or is this in the upper third? This is key in understanding what a posterior repair is. Not all posterior repairs are the same.
You have posterior repairs that are done in the lower third or in the upper third, and they're two different types of surgery.
Q. And --

A. They all get placed on the bucket of the posterior repair, and that's something that over time we'll figure out and we'll have better -- better data and better -- better studies on it.
Q. And where was Ms. Cavness's prolapse?
A. It's -- it extended. It had -- when you have a detachment of the muscle, you just don't have a -- a posterior -- posterior defect. You have an opening hiatus. You have an opening post -- a dilated posterior lower third, and it extends to the mid and upper -- upper third. It extended through the whole extent.
Q. So if we're looking at our diagram, where would her weakened tissue have been?
A. In the -- in the whole posterior.
Q. Do you have your pointer?
A. Yes.
Q. Okay.
A. Oh, yeah, yeah, yeah. It's -- this was open, but this is the one that -- it's always a challenge, so when we saw go back to location, to the L of RULES, the location, upper third vaginal defects have a higher chance of coming back, upper third. If you look at the -- at these repairs down here, you repair them, and the patient doesn't -- doesn't usually come back. They're happy with it.

You do it here, and since you don't have a whole lot of tissue up here, patient comes back with a recurrence. So part of the RULES, when you consider -- when you either contemplate using -- using a graft, the L of the RULES is the location, where's my prolapse located?
Q. E?
A. E is, is it external or internal? You operate into someone that has a prolapse that is in the inside of the vagina that they just feel occasionally, they respond differently than someone that has a prolapse that comes through the outside of the vagina.
Q. And is that the staging?
A. That's the staging, but instead of getting into the -- the suit letter of the stagings, very simple, if your prolapse is -- is inside, you have a lower rate of recurrence with your repair. Is your prolapse -- prolapse is already outside, the recurrence is higher.
Q. And what's the last factor you considered?
A. The size, S. That's the final -- the final letter on the -- the -- on the -- the size. You have a prolapse that is larger than 2.5 centimeters, larger than 2.5 centimeters, and you have a higher rate of recurrence. Why is that? How -- how we learn that? We learned that from experience. 2.5 centimeters is the

actual opening. When you measure the gen- -- the genital opening, when you measure -- measure the vulva opening, it's 2.5 centimeters.
If you're prolapsed, it's bigger than that. Obviously it has stretched outside. That's what the S is, the size of the prolapse. Not all prolapses are managed the same. So when you have -- you're looking at a prolapse, you look at the RULES, and those are the RULES that are going to determine how to counsel my patient before I take her to the operating room.
Q. And apply these rules to Ms. Cavness --
A. In Mrs. Cavness --
Q. -- in April of 2012 when she went to see Dr. Kowalczyk.
A. In April 23rd, 2003rd (sic), Mrs. Cavness had the factor of the uterus being taken out. There -- there are -- what was described is different all the way to the upper part. There's no actual description of rugae, but I don't see rugae in the upper third when someone comes with a detachment like that.
The location was described in the upper two-thirds. The fact that it came external, she felt it on the outside when she came to the emergency room, that was the most frightening thing, and the -- the size of the prolapse is associated to how external it is.

Those -- all of them, when -- when I -- when I read the medical records, I read the description of the operative report, all of them are filled, the RULES.

Q. Now, are there -- were there other options available other than PROSIMA™?

A. At -- at the moment -- moment of her -- of her surgery, you could have done a native tissue repair. But the native repair under these circumstances carry a higher rate of recurrence.

Q. And just tell the jury what a native tissue repair is.

A. Native tissue repair is when you take -- the same tissues that broke down are going to put it together. You take the same tissues that are behind the prolapse, and you're going to rely -- after they broke, you're going to rely on -- on -- on the scar tissue. We call that scar tissue.

We hear scar tissue, scar tissue, and scars are not always just as a scar. This -- when we -- the body's a lot smarter than that, and the body produces fibrosis. So from now on, I may be referring to it as fibrosis. That's the actual term, "fibrosis."

Q. And fibrosis meaning the scarring?

A. Fibrosis, yeah. But a scar is a scar, and we can confuse it, but it's a fibrosis.

Q. Do you have a PROSIMA™ up there?

A. Yes, I do.

Q. Okay. Is that the actual size?

A. This is the actual size.

Q. All right. Can we have the --

(Off with co-counsel)

Q. And, Doctor --

MS. GALLAGHER: Your Honor, may he step down?

THE COURT: He may.

Q. (BY MS. GALLAGHER) And, Doctor, what is this that I'm handing to you?

A. This is the inserter, a similar inserter from what was used to insert the PROSIMA™ on Mrs. Cavness.

Q. And is -- show the jury how that works.

A. Okay. So -- so the way it's -- it is designed is it has a blunt end, so you -- I guess if someone has the idea of penetrating anything, they will not be able to. And -- and -- and it has that blunt end, and then mesh is about 10 centimeters, and these 10 centimeters you -- the vagina were really -- I don't know if I defined that it was 12 centimeters, but I said on the length of the vagina. And when -- when you insert it, this design, this upper part here, when you place an instrument to handle it, it doesn't let you go farther

because of this angle. So even if someone has the -- the force or doesn't have the accuracy to go directly, it cannot go any further than this. And this I -- I measured with my fingers 10 centimeters. That's essentially it, so --

Q. Now, the -- and so are you actually taking this and putting it through the incision or the --

A. You put it right here. And -- and when this is connected to an instrument that is -- we use for sutures, this -- this right here, you can -- you connected it, and then you identify the landmarks, that is the easiest way to identify the body landmark, and once you identify the body landmark, you slice it there. Take it out.

Q. And is that the ischial spine that you were talking about?

A. Yeah. That's -- that's medial. We call it medial. We -- medial is the -- to the middle. I do -- I have my patient -- my patient here, and I want to approach her -- her left side. I'm going to do it with this. I'm going to have an instrument connected here. In this angle, the instrument comes up like this, so I -- when I insert it, it cannot go any further than that -- any further than this in here.

It'll stop. It'll stop right there. It'll stop outside. You cannot go any further than

these 10 centimeters. I can -- I could pull my finger and feel the tip, the ultimate PROSIMA™ as it was inserted.

Q. And when you -- you can take your seat, Doctor. When you insert it, are you actually putting it through any muscles or --

A. No.

Q. -- stitching it?

A. No. You can -- you do not -- you do not have a muscle that you insert it. That's -- the device doesn't allow you to do it because it's square here in the -- in the tip.

Q. Now, the jury has seen a picture of a Prolift, which is much bigger, and it has long arms on it.

A. Right.

Q. And let me hand you this, and tell the jury what this is and how this relates to a Prolift.

A. The -- the Prolift is, we're -- we're -- we're placing it from another side. We're placing it from the outside of the pelvis, and for patients to have a very large -- large prolapse, I found it -- I found it very -- very useful, but it's a different procedure. It's a larger procedure.

It's -- it's -- the anatomy sides are different. The approach is different. This is a

different -- different thing. This is a -- comes from the outside, and it looks -- it looks intimidating, and if you're -- if you're -- if you're not a surgeon obviously with a -- with a -- with -- with the expertise on -- on these type of procedures, you're not going to be using this, and --

Q. And does that actually -- is that designed to go through muscle?

A. This one goes through muscles. This goes through about -- about -- through about four or five layers of thick muscle, I mean, the -- the Prolift.

Q. Doctor, the jury has heard through Dr. Margolis that surgery with PROSIMA™ in the posterior or the back of the vagina is not superior to native tissue. Do you agree with that?

A. I do not agree with that.

Q. Why?

A. I do not agree with that for a few reasons. Number one, clinically, and clinically -- and when I say clinically, I mean in terms of surgical anatomy, we identify this -- this kind of things with RULES. We identify there's no -- no tissue in the upper part. I say clearly that not all posterior defects are the same.

Q. What does that mean?

A. You can have a lower defect. You can have a

middle defect. You can have an upper defect, and the higher you go, you will not have that fiber connective tissue under -- under the vaginal epithelium. So that just validated -- that principle has got invalidated on the letter on the -- that became an article that over 600 surgeons sent to the FDA in 2011.

That article, they made reference to four randomized control trials in which it is clear that these patients have a lower rate of recurrence when the repair of the posterior compartment is reinforced with a synthetic graft.

Q. The jury also heard from Dr. Margolis some comments about stiffness of the mesh. Is stiffness good?

A. I -- I -- I could not answer yes. I would have to explain that.

Q. Please do.

A. There's a degree of stiffness. There's a degree of stiffness that -- that you need, and it -- we use -- we use the term biomechanics, the movement, the biological movement of things. And the -- there's -- when I explained before that these muscles have to have certain pliability and certain elasticity. It's like the shock absorber in a -- in a vehicle. You just -- it needs to -- it needs to move.

Q. And when you're saying "it," you're talking

about what?

A. The muscle -- the muscle -- the muscles that I described before in the pelvic floor, it needs to move. When you're -- when you're doing squats, when you're exercising, when you're walking, when you're sneeze, when you're doing all these activities, they need -- they need to move like a shock absorber. If it's too stiff, it doesn't -- it doesn't move properly. That's the contracted muscle.

If it moves too much, the prolapse comes in. So there's -- there's a -- there's a degree of stiffness. Now, how do we grade that stiffness? There's -- there's evidence that -- of the stiffness index.

Q. What's a stiffness index?

A. Stiffness index, like any -- any index you hear all the Bloomberg and there's marketing index. Stiffness index is the actual quantification on how stiff something needs to be. That stiffness index, when you have -- when it was measured on a small population of patients, the stiffness index that was on the highest provided the best -- the best support for patients that have prolapse.

Now, there's -- like in everything else, there's no zero; there's no 100. You have to have something in the middle that would give that pliability,

that elasticity. And that's what the -- those are the preliminary studies on stiffness index. They went further, and they saw that stiffness index can be correlated with quality of life symptoms for prolapse.

Q. Explain that.

A. Everything that we do translates into how we are going to feel. Nobody has surgery to feel worse. People have surgery to feel better. And that stiffness index, you need it. Otherwise, the patient will come back with a prolapse, will have that prolapse coming back at -- coming back and give symptoms.

It feels -- it feels -- over 26 years, I've learned that my patients that have those symptoms, they feel that bulging coming out, and that's not a good sensation for anyone.

Q. Dr. Margolis also talked about the heaviness and density of PROSIMA™. In your opinion, is the PROSIMA™ too heavy or too dense?

A. The -- at that time, they -- they -- the implant, the synthetic graft, with the largest body of evidence in the pelvic floor was the material used in PROSIMA™.

Q. How about Dr. Margolis's comment that PROSIMA™ deforms or shrinks or contracts?

A. There's -- that -- that has been -- was

addressed on the same communication that I just referred to.

Q. What -- and tell the jury a little bit more about that communication. Is that what I was asking?

A. Well, the communication was the FDA came in, and there was a panel of about 12 people on the -- on the -- on the FDA that say, listen, we have -- we have gone through these studies, and based on what we're -- what we're seeing, there's no benefit on using -- on using -- or there's no clear -- clear -- it was no clear benefit in using a graft.

But then we knew -- we knew as surgeons that use graft because obviously there's -- there's -- we are -- we are the ones with the largest experience. As surgeons that use graft, we say, well, wait, we have a -- we have different experience using graft. We're not saying that graft are the best for every single case. We -- we understand that. We -- we know -- we know what -- we have a way in our surgical knowledge on how to choose who's going to use it, who's going to benefit from it.

But on the -- on the other -- on the other -- on the other side, this -- this graft -- this graft have not been shown to -- shrinkage or the formation, all these things that are being -- that are

being told because we have four -- actually 40 patients followed by ultrasound and four randomized control trials in which it shows that there's no shrinkage.

In clinical terms, in very simple terms is we have not seen vaginal shortening. If the patient would have a shrinkage of the mesh and the mesh still there, there should be vaginal shortening -- the vagina would be shorter. And we have not seen that, and we did not see that in Mrs. Cavness.

Q. How about degradation. Dr. Margolis talked about -- talked about degradation.

A. The -- the deg- -- the degradation, it's -- it's a concept that has been shown only on one study. It was done with PROSIMA™. And it was on a study in which the specimen itself was used. The material went through a long process before you could conclude that. There's no actual evidence of in vivo degradation that we can use in our -- to my knowledge, that we can use for clinical use.

Q. What's in vivo?

A. In a living person, so -- and it's going to be very difficult to obtain that in a living person.

Q. Dr. Margolis said that if you used PROSIMA™, you have a higher incidence of a -- of another posterior mesh repair. Has that been your experience?

A. No.

Q. Are you aware of any clinical evidence or any literature that supports that?

A. No. It -- we -- we have seen with native tissue repairs, repairs with a mesh and without a mesh -- repairs with a mesh and without a mesh, there's going to be -- because of the -- of the lack of collagen and content in the tissues, you can see a prolapse. And it's going to come out through an area that is not protected, and the -- so if you protect one area with -- by placing -- placing a graft, you protect that area, the area that is not protected is going to receive pressure. It may prolapse.

Q. All these things that Dr. Margolis talked about, things like degradation and the other things he had on his chart, did you see that any of those issues had anything to do with Ms. Cavness?

A. No.

Q. You know a lot about Ethicon products?

A. Yes.

Q. And we talked a little bit about this before that you started by attending the cadaver labs or the specimen labs.

A. Yes.

Q. How long had you -- was it that you'd been

attending before you started teaching in those labs?

A. Well, I -- I started attending those -- those labs and placing the instruments, but I would stay longer. I would ask for permission to stay longer on the -- on the cadaver -- cadaver labs. And after everything was placed, I would just dissect the area and make my notes. And it's -- it -- for some -- for a -- for a surgeon, it's really difficult to get access to a cadaver lab unless you are in an anatomy department at -- at a medical school. So I -- I started doing those -- those work.

Now, after that, it was -- it was probably a year and a half, two years that they -- they saw me working on it and they asked me would you like to come in, and I wasn't going to start teaching off the bat. You know, I would see how other people taught the lab, and I would help the surgeons that would come in and -- and dissect in the -- in dissecting the cadaver, in dissecting the specimen.

Q. When did you start doing that?

A. Around I would say the first -- the first few labs, 2003, 2002, maybe earlier.

Q. And when you were teaching at these cadaver labs, what's involved in that? I mean, do they come -- they don't come to your office?

A. No. It's a lot of work. You travel there.
Q. You travel to where?
A. You travel wherever the lab is being done. Because not -- you don't have a lab in every community. You -- you travel to where the lab is. You go to your -- you -- you spend a night in a hotel, and let me clarify. It's not a luxurious hotel, no.
Their -- their rules and their guidelines, they're not going to put you in a resort. So you stay there, and the next day you work, and don't even think about staying after the lab, about staying over the night in the hotel, no. They'll get you out, and you're going home. And obviously when you come home, then you have your -- your practice that you have to attend. You have your phonecalls. You have your other patients that -- that you take care of.
Q. And when you're teaching these labs, tell the jury what you're doing during the daytime as a teacher.
A. You -- you get up early. You -- you attend the -- the lectures. You sit there and give -- I like to -- to give a diagram of this is what we're going to do to my -- to my two or three doctors that I may have on the -- on the specimen. This is what we're going to do, and I -- this is where I'm going to take you, and this is -- I'm going to show you at the end once you identify

all this and I see that you're proficient at it, and I'm going to -- I'm going to show you how to place it. And then we can -- we can -- we can -- we can hope to place the device, and then we can go through it.
Q. Why did you do this?
A. Because it -- it gave me the only opportunity to interact with my peers at that level. It gave me the opportunity to dissect cadavers and dissect specimens and make myself better.
Q. How often did you do these cadaver labs, did you teach these cadaver labs for Ethicon?
A. They -- there would be -- there would be -- there were years that were like one -- one -- one every month, and there were times in which it was more frequent than that. There were times obviously in which was less frequent, so it change according to the -- I did not determine how frequent. They would just tell me how about going to this lab or this other lab.
Q. And what -- what were you paid for teaching an entire day of these cadaver labs?
A. I -- I got paid, I believe it was $3,000.
Q. Did it change over the years as to how much you were getting paid?
A. No. It was -- it was about the same -- the same rate. It was -- that was for the -- for the full

day. It did not include the travel the night before. It did not include my gasoline, if I drove, or -- and they did they did cover the airfare. But I can't -- they did not cover the expenses of my office while I was away.
Q. All right.
A. That's for sure.
Q. And --
A. But I got to dissect cadavers.
Q. Over the years, do you have an estimate as to about how much you made or were paid for -- by Ethicon for teaching in these cadaver labs?
A. I -- I -- I got paid on -- on the -- there were a few -- a few things. I would teach the cadaver lab. I would be invited to activities where -- where the reps at Ethicon wanted to learn about cadaver dissection.
Q. Okay. Let's talk about that for a minute. That's something separate and apart from the cadaver labs?
A. Right.
Q. Tell the jury what you were doing then.
A. It's a -- when -- when they -- they had their -- their sales force, the people that was actually going to be selling the product, they would come in and dissect with me. And it was a -- a big privilege for them to be able to dissect with me and the cadaver, and I

would teach them, okay, this is where your product goes. This is how it's used. This is how -- this is how it's placed. That's -- that's what they wanted to learn.
Q. And those were for the sales representatives?
A. Yes. They could be -- they could be sales -- sales representatives. They could be the engineers.
Q. The engineers. What engineers?
A. There's a -- they're -- they're material science engineers that --
Q. Who worked for?
A. -- who worked for Ethicon. And they did not just work on -- on PROSIMA™ or one mesh. They would just see all this range of material science, and they would come in and -- and do the lab with me.
Q. What other activities did you do for Ethicon?
A. I -- I also look at their -- at their manuals to dissect. I look at the -- I put together a book on -- a book on the use of a graft with -- with -- with diagrams. I -- I would look at presentations. It's -- it's -- it was all -- all these activities I have to do with -- I publish -- I publish -- we put together a white -- white paper.
Q. What's a white paper?
A. A white paper is an instructional paper. It's not an experiment or study. It's a study. White paper

is something we're -- it's a document in which we describe how to get a technique accomplished. And this -- we call it a white paper because there's no statistical summary. It's -- it's an opinion among the among the expert.

So we put one that had nothing to do with the device, with any device. It had to do with how to approach the anatomic landmarks on the pelvis with -- with minimal blood loss and with accuracy using -- letting your -- your solution, your water dissect for you, injecting a solution and then putting everything -- blowing everything and then opening and being able to approach all this -- all these areas without blood loss.

Q. Is that called hydrodissection?

A. I -- I -- I call it hydrodissection. It took off.

Q. And you what?

A. It took off. Everybody started calling it hydrodissection, and now it's known as hydrodissection.

Q. And other doctors use that method?

A. For all surgeries, for every surgery. Who wants to -- everybody wants to decrease the blood loss.

Q. So going back to over the years that you've worked for Ethicon, can you estimate on average how much money you made per year doing these various activities

and teaching and writing?

A. About a hundred thousand dollars a year.

Q. Were there years that you made a whole lot more than that?

A. I may have done more than in some years that I was -- I was busier. I actually went and checked with my -- when the question came in, I -- I checked with my -- my accountant. I asked him. He could not give me a specific number because I -- I get income from other sources, all the other things that I. Do but from Ethicon, I would say it's safe to say a hundred. There are years that were more. There are years that might be less.

Q. But --

A. Did I keep track of it? No.

Q. And the amount you were paid would just depend on how many activities you were doing, for example, how many cadaver labs you were teaching?

A. Oh, you got -- you got to work. If you don't -- you got to put the time. If you don't put the time or work, you don't get paid.

Q. And did Ethicon ask you to do these activities? Did they first approach you, or did you approach them?

A. No, they approach me.

Q. And when did they first approach you?

A. It may -- may be for -- for these activities that involve more. It's -- it was probably after I went to see with the -- with the higher activity after I went to see Professor Cosson in France use transvaginal mesh.

Q. All right. Let's get back to Ms. Cavness.

THE COURT: Let's go ahead and break here counsel, for about --

MS. GALLAGHER: Yes, Your Honor.

THE COURT: -- 15 minutes.

THE BAILIFF: All rise for the jury.

(Jury out)

(Recess taken)

THE COURT: Could I have you bring some water for the jurors?

MR. CAPSHAW: Yes, sir.

THE COURT: I typically ask both sides. I don't know if they sent out the letter this time. They may not have, but I always ask each side to bring a couple of cases of water.

MS. GALLAGHER: We have, Your Honor, and we've got more back here.

THE COURT: Okay. Wonderful. If we've got more, why don't we just get them.

MR. CAPSHAW: Do you want it now, Your Honor?

THE COURT: Yeah. They're out.

(Off the record)

THE BAILIFF: All rise for the jury.

(Jury in)

THE COURT: Take your seats, please. Come on back up and join us, Doctor. You may continue, Ms. Gallagher.

MS. GALLAGHER: Thank you, Your Honor.

Q. (BY MS. GALLAGHER) Dr. Sepulveda, I want to stitch topics with you for a minute and talk about the information that comes with a device like a PROSIMA™. You're familiar with IFUs, instructions for use?

A. Yes. I'm familiar with them.

Q. What are those designed for?

A. Instructions for use is a guide for the -- how -- how the -- the device is placed.

Q. Would you expect somebody who has never placed a PROSIMA™ to just open up the package, pull out the IFU and start doing surgery?

A. No. I would not expect that.

Q. Why not?

A. Because you need to -- the -- the device doesn't do the surgery. You do the surgery. You use the device to complete your surgery. So you have to know the details of the surgery before you use that device.

Q. And the IFU contains information about complications and risks?
A. It does -- it does mention those -- a few of the complications or potential risks.
Q. Is that the only source of information about potential complications and risks of any surgery or the device?
A. Absolutely not.
Q. Where else do doctors get information from?
A. In medical school, in residency, in your fellowship, on your instructions, on the books that you read every time a new edition comes in, and in your -- in your journals, in observing other colleagues, and from your own clinical experience.
Q. Have you reviewed the IFU warnings and adverse events?
A. I -- I have read -- I have read that in the IFU.
Q. Do you think those are adequate to inform surgeons of the potential risks and complications in using a PROSIMA™?
A. Yes, they are adequate.
Q. Now, who has the duty to inform the patient about potential risks or complications with a surgery or the use of a device?

A. It's -- I am -- I am the surgeon. It's -- it's -- it begins and finishes with me.
Q. Why is that?
A. Because I'm the surgeon. I'm going to be the one performing the procedure. I am in charge of the well-being of that patient.
Q. And when you were talking to a patient about the surgery, do you talk to them about things you're not going to do?
A. I -- I talk about the things that I plan to do. That's why I do a physical exam and a history ahead of time.
Q. If you were not planning on using a particular device with a patient, would you spend the time to talk about that device with the patient?
A. There -- there's no -- no reason in this world to overwhelm anyone with an explanation of the surgery that -- or a device that you're not going to use.
Q. So you're only going to talk to them about things you are using?
A. I'm going to talk to my patient about the things that are relevant to me and are relevant to my patient.
Q. All right. Let's get back to Ms. Cavness. I think when we were talking about Ms. Cavness before, we

had gone through why she was in an appropriate candidate under RULES for the surgeries that Dr. Kowalczyk performed.
A. Yeah. Yeah. I -- I concluded that.
Q. So let's talk about the surgeries went fine?
A. Surgery went well.
Q. All right. Let's talk about the time period after the surgery.
MS. GALLAGHER: And, T-Zady, if you could please pull up 10021.13, and if you could blow up the top. I'm sorry, the reason for visit.
Q. (BY MS. GALLAGHER) And, Doctor, you have this on your screen?
A. No, I don't have it. I forgot my glasses this morning.
Q. Oh. Hold on. I can can fix that. You're going to love these.
(Laughing)
Q. I do not go anywhere without multiple pairs.
THE COURT: It was there momentarily.
JUROR: It's not on the screen. His monitor's not working.
MS. GALLAGHER: Oh, I thought --
THE WITNESS: I said here, here. My monitor's --

JUROR: The screen is not on, working on it.
Q. (BY MS. GALLAGHER) You do have glasses?
A. Yeah.
(Laughing)
Q. Do you want the blue ones? You can have the blue ones. I'll wear the red ones, better than not being able to see.
A. I need it here.
THE COURT: I don't know. It was on momentarily. It just went off. Do you have a clue what's -- what the problem is?
THE BAILIFF: No, sir, but that usually fixes it.
MS. GALLAGHER: Is this off? Why is that off, do we know?
THE REPORTER: Mine's on. Mine's on, and usually they're always off.
MS. GALLAGHER: Is yours on, Your Honor?
THE COURT: We can -- we --
MS. GALLAGHER: How about this?
THE COURT: -- we can bring it down and bring it back up.
THE BAILIFF: Michael, Michael, usually if you bring the whole system down.

MR. KAUFFMANN: That's what I'm trying to do.
THE BAILIFF: Start over and bring it back up.
(Off with co-counsel)
MR. KAUFFMANN: Robert, do you think the power could bring it up? The court system's just not starting up.
THE BAILIFF: Shut the whole thing off and start over.
THE COURT: Something happened.
MS. GALLAGHER: Is it not working?
MR. KAUFFMANN: It just takes a second.
MS. GALLAGHER: Is it just not going to work?
MR. KAUFFMANN: It's in this process.
THE BAILIFF: Hasn't gotten off the screen yet.
THE COURT: It's trying to shut down. Are you going to bring it up now, or --
THE BAILIFF: It's not off.
THE COURT: Okay. I just wanted to make sure we weren't hitting different buttons at the same time.
MR. KAUFFMANN: The spinning hourglass.

MS. GALLAGHER: Oh, that's never a good sign, spinning hourglass, Your Honor, sign your electronics are really in trouble. It's --
MR. KAUFFMANN: It's making progress.
THE COURT: All right.
THE BAILIFF: Never seen it not turn off before.
(Judge making phone call).
JUROR: Do you guys in the court for the court systems in general, do you have any engineers or technologists?
MS. GALLAGHER: I think that might be where he's going.
(Off with Coordinator)
MS. GALLAGHER: Your Honor, I have hard copies I could hand to the witness and to you, if you want them.
THE COURT: We'll just do it the old way.
MS. GALLAGHER: All right. Would you like copies of things if I'm going through?
THE COURT: If you have them.
MS. GALLAGHER: I do, Your Honor, I think.
THE COURT: I'll see if I can't get our IT tech up here.
MR. MATTHEWS: Ms. Gallagher, I think the

Elmo works.
MS. GALLAGHER: The issue is their screens. We're fine.
JUROR: Doctor.
JUROR: Maybe try turning it off and then turning it back on.
THE WITNESS: Twice, on -- the connections back here always come loose.
JUROR: Oh, got it. Oh.
JUROR: Looks like it's loose.
JUROR: There was over there.
JUROR: There we go.
MS. GALLAGHER: It's going on and off.
JUROR: It's going on and off up here.
JUROR: Yeah, it's a connection over there.
JUROR: There it goes.
JUROR: And then back on right there. There it is.
JUROR: We got it.
JUROR: There.
JUROR: It's a connection. Yep, a connection.
THE WITNESS: Yeah.
JUROR: There.
JUROR: You can plug --

JUROR: You're doing something.
JUROR: There it is.
JUROR: Yeah, there you go.
JUROR: That's it.
JUROR: There.
JUROR: Stay just -- stay right there.
JUROR: So it's right there.
MS. GALLAGHER: Michael, you can't move. You have to stay right there.
(Laughing)
THE WITNESS: Okay.
JUROR: I went away again.
THE COURT: All right. We'll see what we can have done at lunch.
MS. GALLAGHER: Is it not working? Okay.
MS. GALLAGHER: Are you ready?
THE REPORTER: Yeah.
Q. (BY MS. GALLAGHER) Doctor, given our technical difficulties, you can't see it on the screen, so I've just handed you the actual -- a paper copy of the record. Do you see this?
A. I do.
Q. And in this record, this is the first time that Ms. Cavness comes back after having had her various surgeries with Dr. Kowalczyk; is that right?

A. Yes.
Q. All right. And she's coming in at this time for what reason?
A. She's coming for a postop examination after posterior repair, plication and PROSIMA™.
Q. And what is her issue?
A. The patient -- Dr. Kowalczyk documents that Mrs. Cavness felt a foreign body in the vagina.
Q. And what is she feeling?
A. The vaginal support device.
Q. Tell the jury what the purpose of the vaginal support device is.
A. The -- once -- once you place an im- -- this implant for PROSIMA™ specifically, for PROSIMA™, and the implant sits in there, there's -- there's no actual sutures or attachment to it. So -- so when -- since it's tension-free, we call that tension-free, and tension-free in general means that a -- the -- the -- graft is not being distorted on its normal shape. That's one of the requirements for tension-free.
But while -- when the patient -- when the patient stands up and she starts walking around, your -- the -- this -- the vagina will move. And the -- the pressure -- the abdominal pressure that we all generate when we walk around and when we -- when we move, we

just -- we just move the graft. So it takes about three to four weeks for the tissue to -- to get a nice ingrowth in between the pores and around the small fibers.
It takes it takes about 21 to 28 days, so the vaginal support device stabilizes the graft, and it -- it allow -- it -- it allows for me to place the graft without putting a suture to hold it. That's -- it's -- it holds the graft in place with all -- regardless of the other movements that the patient may have on doing her dale -- doing her activities.
Q. And did Ms. Cavness have any issues with the vaginal support device staying in place postoperatively?
A. No.
Q. Was there a time when Dr. Kowalczyk had to replace a suture?
A. There was one suture that came loose. It -- it happens when the suture comes off from where it has been placed to hold -- to hold the vaginal support device.
Q. And that's my question. The suture that Dr. Kowalczyk replaced for the vaginal support device had nothing to do with the actual PROSIMA™?
A. That's correct.
Q. Now, I want to talk to you about the explant surgery that Dr. Carley did. But I want to talk to you

about something that was happening before that in June.
Do you recall that it was early June when Ethicon announced the de-commercialization of PROSIMA™?
A. I -- I recall that.
Q. Well, what was the reaction? Describe that period for you as a urogynecologist.
A. Well, it's -- we -- we had -- we had an option in the patients that -- we had an option --
MR. MATTHEWS: Judge, I would object as to relevancy. This was post-implant -- explant.
THE COURT: What's the relevance of that?
MS. GALLAGHER: Your Honor, it's going to go to his perceptions of a tunnel vision that a lot of uro- -- or gynecologists had after that of problems with mesh. It goes to the whole looking -- the differential diagnosis of the various doctors going through the rest of Ms. Cavness's chronology.
THE COURT: Sustained.
Q. (BY MS. GALLAGHER) Doctor, let's move to the July 2012 explant that Dr. Carley did. All right. And can you tell the jury just generally what surgeries Dr. Carley did?
A. He -- Dr. Carley went ahead and removed the -- the implant, and during the removal of the implant, he identified defects that -- the defects in the area, the

prolapse. He identified the prolapse, and he went ahead and sutured this, and did a suture repair with -- with a non-absorbable suture.
Q. And explain to the jury the difference between nonabsorbable, absorbable and absorbable sutures.
A. Oh. We -- we have a -- we have in our trades, we have sutures that are absorbable. They're absorbable, means that they would disappear. The fibrosis will take -- will take over for the force of the suture. We have sutures of different calibers. We have sutures that are nonabsorbable, and we have sutures that are with multiple filaments, very tiny filaments put together. And we have sutures that are just one filament, one -- one single filament.
Q. And are some of those sutures designed to stay in the body forever and some go away?
A. Some of them are going to stay, you know, stay forever. And they're going to -- they're going to be adapting to the body, and they will stay there, and some of them are absorbable.
Q. Explain to the jury the procedure that Dr. Carley used to remove the mesh from Ms. Cavness.
A. Dr. Carley opened the -- the vag- -- the vaginal covering using over -- over the implant and dissected it out, and that's -- that's a very -- that's a

very standard procedure, dissected it out and then went through this arm and this arm, and he describes that he -- he pull it and pulled the implant out.

Q. Did he do that in one piece or more than one piece?

A. He -- I checked the pathology report, and although he does not describe in his operative report that it was in one piece or multiple pieces, the specimen, what comes out is in multiple pieces.

Q. Now, Doctor, you talked about the surgery that Dr. Carley did afterward.

A. Yes.

MS. GALLAGHER: And, Your Honor, can I have him come down and draw this?

THE COURT: You may.

Q. (BY MS. GALLAGHER) And, Doctor, you're going to have to have me hold this because I lowered these for the timeline, so maybe we can prop it up here. Can I get another color?

(Off with co-counsel)

Q. Okay. Go back to our blue woman. I'll hold it, if you'll draw.

A. Do you have a green one?

Q. I think you have the green one up there. Up there --

A. Oh, there.

Q. -- by my glasses --

A. Yeah.

Q. -- that you're refusing to use.

(Laughing)

A. Just green one.

Q. Okay. So first, if you would, would you draw in where the mesh was originally placed?

A. It was placed this -- it was placed right around here, here to here.

Q. All right. Now, the surgery --

A. That's -- that includes a little arm like this and might be a little shorter than that space on basic description.

Q. Now, would you explain to the jury the -- is it a USL, uterosacral ligament suspension, that Dr. Carley performed after he removed the mesh?

A. He removed the mesh, and now he sees that there's a prolapse right -- right up here on the upper -- on the upper third of the vagina, in the upper two-thirds. This is the rectum. This is the vagina, and it's right here, right in here. And then he sees that this is coming down, and that this vaginal cuff was going to come down, and it's like -- if you take one of your -- of your socks and invert it out, you know, it would just

eventually come down in here.

So when you -- what you do is with the uterosacral ligament suspension is you go higher, and then you put a stitch on top of here. And that's -- there are two stitches on those that he placed up -- permanent suture.

Q. And that's what you're doing in the green marker?

A. In there, and, yeah. So -- and there -- and there -- and I'm putting the stitches up, and I'm bringing it down, and then when you cinch them down, what you have left is this, this suture, but there are more than just two sutures. There were another -- I'm not -- I'm not going to put a loop. I'm just going to put a line --

Q. Okay.

A. -- with these sutures. One -- one suture from here, here to here, and a suture is a stitch, and one from here to here, here -- another one from here into here. And the last one is a permanent suture. These were absorbable permanent sutures right here, and the same thing happened on the other -- on the other side.

Q. So --

A. There was a suture from here, and then there were three other sutures that were absorbable. So the

whole -- all this -- all this is covered. Three -- three sutures on one side and six sutures in total of the vaginal cuff with three sutures on each side.

Q. Now, Doctor, in order for Dr. Carley to get to this area to put the sutures, all right, where is he going through to do this?

A. Well, you -- to get to the next building, you have to cross the street, and the street is basically the spine --

Q. All right.

A. -- across -- the mesh was -- the mesh was here, and you can -- you can count on the -- on the mesh. You can could 6 centimeters maybe, mesh in here, but you have to get up here. So -- but that's -- the inserter doesn't let you place the mesh longer than 10 centimeters in.

Q. Which would be where?

A. At the level of the ischial spine.

Q. And where is the ischial spine?

A. Right here. But you have to go higher than that to put the stitches.

Q. And when you say go higher than that, are you staying on the same plane?

A. Yes. You're go on the same plane. You open --

Q. Describe to the jury what that means.

A. When you're looking -- look at it -- this the

floor of the vagina. You're going in this plane, and then you go up and dissect it out, and that's what is called areolar connective tissue, is very thin tissue that just opens up.

Q. So first Dr. Carley removed the mesh?

A. Right.

Q. All right. And then after he removed the mesh, did he have to go through the exact same area to do the USL sutures?

A. That's a suture -- that's a suture that the other sutures that came in the -- when he was going to repair the enterocele and the rectocele, it comes out like this with our suture. That's the green suture.

Q. And you've drawn that in the green. Why?

A. Because the suture is green.

Q. Is that a permanent or an absorbable suture?

A. That's a permanent suture.

Q. All right. So tell jury where -- just summarize where are the permanent sutures and where are the absorbables.

A. There's a permanent suture right here on the division of the rectum and the vagina. And there's a permanent suture on each side of the uterosacral ligaments, on each side, one to here and one to here.

Q. Thank you, Doctor. Now, when Dr. Carley did

the explant, the mesh removal, did he think he got it all?

A. Yes.

Q. Now, the jury has seen a diagram where there's a picture of the PROSIMA™ that's actually bigger than a real PROSIMA™, and it's got a little square cut out of it. You -- you've seen that?

A. Yes.

Q. All right. Explain to the jury why you think Dr. Carley got all the mesh.

A. I -- I -- my opinion is that there are -- there's more than one -- one reason why he got it all. Number one is you look at the measurements of PROSIMA™. In between -- between each blue line is 2 centimeters, so there's 1, 3, 5, 7 centimeters, and it's 7 centimeters up to here. Then you have another two plus maybe one here. So it doesn't go beyond 10 centimeters.

Let's say the PROSIMA™ will be longer than 10 centimeters. You cannot insert it longer than 10 centimeters with this inserter. The inserter doesn't go deeper. It can -- the inserter cannot go -- cannot come in here if it -- if it stops right here, so --

Q. Why is that significant? Explain that to the jury.

A. That is significant because it speaks about how

far I can go with this instrument. Now, I have explained already that the instrument comes right here, so it's not like I can just take it and just shut -- put it up there. Actually, it's made in a way that is not sharp. It's made in a way that is not sharp. You cannot -- you cannot really go as far.

So you cannot go longer than 10 centimeters. It's not like you're penetrating anything. So when you do a high uterosacral ligament suspension, you're going higher than that. You're going higher than your 8, 10 centimeters. The uterosacral suspension is up here.

So to get the mesh, all you have to do is get your finger and you get right to the tip of the mesh. All you have to get is to get your finger up. This idea that there's a mesh lost somewhere or embedded somewhere, that's not true. I can get it to my finger, and that's -- that's the distance.

Q. How pathology slide that measures it at by four by three or whatever the pathology measurement is?

A. So this is what happens. You have your implant in place. It's surgically inconceivable that I'm just going to take this and just take it like this because that -- and in one piece. It needs surgically inconceivable because there's an interaction of tissue,

and you want that when you place an implant. You have an interaction with the tissue.

More importantly, this surgery was done at 7:00 in morning. The operating report is dictated at 7:09, at 7:09, and the specimen is reported as examined at 5 o'clock. Now, this is not like the -- the -- it was perfectly preserved. That -- that mesh has tissue inside, so now you're going to drop it. Now, you're going to drop in formalin.

Q. What is formalin?

A. Formalin is a desiccating agent.

Q. What is a desiccating agent?

A. It takes all the water and contracts the fibrous tissue. So now you're going to put this specimen on formalin at 7:00 in the morning and now at 5 o'clock, you're going to expect to take something out, and you expect everything to be unfold. It's not -- it's not possible. There's tissue in between each pore. This -- this mesh was well-incorporated. It was -- it would have tissue in the pores, and when the tissue desiccated, it brought it down, and in every single specimen, you're going to see that that tissue contracts. The tissue contracts. Just -- you just place it for that period of time on formalin 50 percent.

Q. Now, Doctor, after the explant, did Ms. Cavness

continue to have problems?
A. She -- she continue with -- with pain. There were no issues with the mesh.
Q. In September, did she have to have -- 2012, did she have to have a suture removed?
A. That's correct.
Q. Explain to the jury what was involved in removing that suture and where that suture came from.
A. After that surgery in which that suture was placed, there's an office note in which a green suture was removed from the area where it has been placed in the -- in the vagina.
Q. And is that the same green suture -- one of the same green sutures that you drew on this diagram?
A. Yes.
Q. All right.
A. It's -- no. The green sutures is -- is specifically the one that was placed right down here. You cannot access these ones up here. You can access only the one is down here.
Q. Ms. Cavness had another surgery in April of 2013.
A. Yes.
MS. GALLAGHER: And, T-Zady, if you could pull up, please, 1004.123.

(Off with co-counsel)
THE COURT: Folks, let's just let that hang there. I've got the -- I think the AV guy from the County over here. We're going to take lunch right now, so I'm going to see you at 10 after 1:00, see if we can get this fixed.
THE BAILIFF: All rise for the jury.
(Jury out)
(Recess taken)

STATE OF TEXAS)
COUNTY OF DALLAS)
I, Deana K. Rouse, Official Court Reporter in and for the 95th District Court of Dallas County, State of Texas, do hereby certify that the above and foregoing contains a true and correct transcription of all portions of evidence and other proceedings requested in writing by counsel for the parties to be included in this volume of the Reporter's Record in the above-styled and numbered cause, all of which occurred in open court or in chambers and were reported by me.
I further certify that this Reporter's Record of the proceedings truly and correctly reflects the exhibits, if any, offered by the respective parties.
I further certify that the total cost for the preparation of this Reporter's Record is undetermined at this time.
WITNESS MY OFFICIAL HAND this 30th day of September, 2015.

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